K070050

MAY 23 2007

Summary of Safety and Effectiveness

Date: April 18, 2007

Manufacturer:
Encore Medical, L.P.
9800 Metric Blvd
Austin, TX 78758

Contact Person:
Teffany Hutto
Regulatory Affairs Specialist
Phone: (512) 834-6255
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Email: Teffany_Hutto@encoremed.com

Product	510(k) Number, Clearance Date, Classification	Product Code
CLP I (Q System 28 Hip Stem) & CLP-R	K910010 – March 12, 1991 Class II	LWJ
All Poly Acetabular Cup	K934169 – May 3, 1994 K942611 – September 28, 1994 Class II	JDI
Foundation Cemented Hip Stem	K935449 – March 30, 1995 Class II	JDI
Bipolar	K953510 – August 9, 1995 Class II	KWY
Vitality Hip Stem	K962560 – September 19, 1996 Class II	JDI
Foundation Press-Fit Hip Stem & CoCr Femoral Heads	K973302 – December 2, 1997 Class II	LPH, LZO
Unipolar with Modular Neck Length Sleeves	K973614 – December 18, 1997 Class II	KWL
Revelation Hip Stem	K973685 – December 19, 1997 Class II	LPH
Foundation Fracture Hip Stem	K973809 – January 2, 1998 Class II	LWJ
FMP Acetabular Shells (Spiked, Hemispherical, and Flared)	K974093, K974095, and K973119 – January 28, 1998 Class II	LPH
Linear Hip Stem	K974294 – January 12, 1998 Class II	LPH, LZO
Stamina Hip Stem	K980473 – April 16, 1998 Class II	LZO, LWJ, KWY
Keystone Modular Hip Stem	K000521 – May 10, 2000 Class II	LPH
ALFA II (Omega II Modular Total Hip System) & Modular Femoral Neck	K000817 – June 8, 2000 Class II	JDI, LPH
R120 (R120 Modular Total Hip System)	K011774 – September 5, 2001 Class II	JDI, LPH
R120 PC (R120 Modular Total Hip System)	K021822 – July 23, 2002 Class II	JDI, LPH
FMP Constrained Acetabular Liners	K023794 – April 1, 2003 Class II	KWZ

Product Code	Regulation and Classification Name
LWJ	Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis per 21 CFR 888.3360
JDI	Hip joint metal/polymer semi-constrained cemented prosthesis per 21 CFR 888.3350
KWY	Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis per 21 CFR 888.3390
LPH	Hip joint metal/polymer/metal semi-constrained porous coated uncemented prosthesis per 21 CFR 888.3358
LZO	Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis, per 21 CFR 888.3353
KWL	Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis per 21 CFR 888.3360
KWZ	Hip joint metal/polymer constrained cemented or uncemented prosthesis per 21 CFR 888.3310

Summary of Safety and Effectiveness – cont.
Encore Medical – Hip System IFU

Description: The modification consists of a change to the Instructions for Use for the devices listed above to minimize the necessity for multiple IFU's and to update the contents to reflect current practice.

Joint replacement is indicated for patients suffering from disability due to:

- noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis of the natural femoral head;
- rheumatoid arthritis;
- correction of functional deformity;
- femoral fracture

This device may also be indicated in the salvage of previously failed surgical attempts.

The Encore hip systems are for total hip replacement except for the bipolar or unipolar hip systems which are for hemi-arthroplasty applications. The CLP Offset, CLP-R, and Stamina hip systems are for either total or hemi-applications.

The following Hip Systems are for Cementless application:

Linear	Stamina
Foundation Press-Fit	CLP Offset
Keystone Modular	CLP I
Revelation	Foundation Fracture

The following hip systems are for cemented application:

Vitality	Foundation Cemented

The following hip systems are for either cemented or cementless applications:

Alpha II	CLP R
R120	R120 PC

Comparable Features to Predicate Device(s): Features comparable to predicate devices include the same materials, design, indications, packaging, and sterilization.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Encore Medical, L.P.
% Ms. Teffany Hutto
Regulatory Affairs Specialist
9800 Metric Boulevard
Austin, Texas 78758

MAY 23 2007

Re: K070050
Trade/Device Name: Encore Medical Hip System IFU
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: LPH, LWJ, LZO, JDI, KWY, KWL, KWZ
Dated: April 18, 2007
Received: May 9, 2007

Dear Ms. Hutto:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

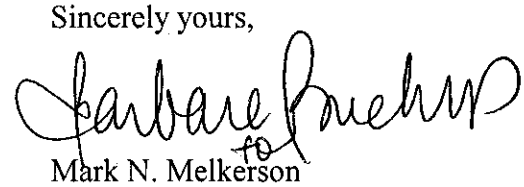
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K070050

Device Name: Encore Medical Hip System IFU

Indications for Use:

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- noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis of the natural femoral head;
- rheumatoid arthritis;
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- femoral fracture

This device may also be indicated in the salvage of previously failed surgical attempts.

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The following Hip Systems are for Cementless application:

Linear	Stamina	Keystone Modular	Revelation
Foundation Press-Fit	CLP Offset	CLP I	Foundation Fracture

The following hip systems are for cemented application:

Vitality	Foundation Cemented

The following hip systems are for either cemented or cementless applications:

Alpha II	CLP R	R120	R120PC

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

(Posted November 13, 2003) 510(k) Number K070050